

PATIENT INFORMATION LEAFLET
ZINC (AS SULPHATE) 20MG DISPERSIBLE TABLET (ZINCOL® 20)

Read all of this leaflet carefully before taking this medication

- Keep this leaflet as you may need to read it again
- If you still have questions after reading this leaflet, ask your doctor, health care provider or pharmacist

In this leaflet you will find information on:

1. What is Zinc (as sulphate) 20mg dispersible tablet and what is it used for?
2. Before you take Zinc (as sulphate) 20mg dispersible tablet
3. How to take Zinc (as sulphate) 20mg dispersible tablet
4. Possible side effects
5. How to store Zinc (as sulphate) 20mg dispersible tablet
6. Further information

1. What is Zinc (as sulphate) 20mg dispersible tablet and what is it used for?

Zinc (as sulphate) is a nutritional trace element required in our body for many uses. Zinc (as sulphate) 20mg dispersible tablet is indicated for treatment and prevention of zinc deficiency. It is used orally together with oral rehydrating salt solutions for acute diarrhea in children under 5 years of age with zinc deficiency. Zinc (as sulphate) 20mg dispersible tablet has been seen to decrease the duration and occurrence of diarrhea. It has also been shown to decrease the chances of hospitalization or death due to diarrhea. Though the action of Zinc (as sulphate) 20mg dispersible tablet in diarrhea is still unclear it is thought to decrease secretions into the stomach, improve water and electrolytes absorption back into the body and increase removal of bacteria/virus.

2. Before you take Zinc (as sulphate) 20mg dispersible tablets

Take special care with Zinc (as sulphate) 20mg dispersible tablet:

If your child has sideroblastic anemia or copper deficiency as these conditions are associated with these high doses of Zinc (as sulphate) in children. Hence inform the doctor if your child has one of these conditions.

Taking other medicines

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Zinc (as sulphate) 20mg dispersible tablet, or Zinc (as sulphate) 20mg dispersible tablets may affect their action.

Oral zinc may decrease absorption of tetracyclines or fluoroquinolones or vice versa hence, Zinc supplements are administered two hours before tetracyclines. Penicillamine and other chelators reduce absorption of Zinc. Calcium salts reduce absorption of zinc. Thiazide diuretics increase urinary excretion of Zinc. Iron supplements inhibit absorption of Zinc and therefore Zinc supplements are administered two hours before iron supplements.

Taking ZINC (AS SULPHATE) 20MG DISPERSIBLE TABLETS with food and drink

Caffeine, dairy products, and bran may decrease absorption of orally administered Zinc. Phytate, which is present in staple foods like cereals, corn, and rice, decreases Zinc absorption from composite meals.

Pregnancy and breast-feeding

The safety of this product in human pregnancy has not been established. Zinc crosses the placenta and will be present in breast milk.

Driving and using machines

Zinc (as sulphate) 20mg dispersible tablet has no effect on patient's ability to drive or operate machinery.

3. How to take Zinc (as sulphate) 20mg dispersible tablet

Always take Zinc (as sulphate) 20mg dispersible tablet exactly as your doctor or health care provider told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The recommended dose of Zinc (as sulphate) 20 mg dispersible tablet for Children 6 months to 5 years is:

Dissolve one full tablet (20mg elemental zinc) in one 5ml teaspoon once daily for ten to fourteen consecutive days at the same time that oral rehydration salts solutions are used.

The recommended dose of Zinc (as sulphate) 20mg dispersible tablet in Infants 2 months to 6 months of age is:

Dissolve half a tablet (10mg elemental Zinc) in one 5ml teaspoon once daily for ten to fourteen consecutive days at the same time that oral rehydration salts solutions are used.

If you take more Zinc (as sulphate) 20mg dispersible tablet than you should

If you have taken too many tablets or if someone accidentally swallows some, you should contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Zinc (as sulphate) 20mg dispersible tablet

If you accidentally miss a dose and notice within 6 hours, take the missed dose as soon as possible. Take the next regular dose as scheduled. If you notice later, then simply take your normal dose when the next one is due. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Like all medicines, Zinc (as sulphate) 20mg dispersible tablet can cause side effects, although not everybody gets them. The most common adverse reactions to oral administration of Zinc salts are nausea/vomiting, heartburn and abdominal pain. These adverse events usually occur during high dose therapy.

Excessive Zinc intake can lead to development of sideroblastic anemia which is characterized by anemia and low white blood cells. Sideroblastic anemia develops as a result of Zinc-induced copper deficiency. These effects are totally reversible following discontinuation of excessive Zinc intake. Other side effects are low blood pressure and fast heart rate, again these are usually seen when one takes higher than the recommended doses.

5. How to store Zinc (as sulphate) 20mg dispersible tablet

Keep out of the reach of children.

Store below 30° C, in a dry environment away from light.

Do not use ZINC (AS SULPHATE) 20MG DISPERSIBLE TABLET after the expiry date which is stated on the label. Do not use ZINC (AS SULPHATE) 20MG DISPERSIBLE TABLET if you notice any visible signs of deterioration.

6. Further information

What Zinc (as sulphate) 20 mg dispersible tablets contains

- The active ingredient is 20mg Zinc (as sulphate)

- The other ingredients are- Maize starch, microcrystalline cellulose, aspartame, ethyl vanillin, colloidal anhydrous silica and magnesium stearate.

What Zinc (as sulphate) 20mg dispersible tablet looks like and contents of the pack

White round tablet with bevelled edges embossed on one side and scored on the other side.

7. Category for Distribution:

Zimbabwe: P

Botswana: S2

Mozambique: Medicamento Sujeito a Receita Medica

Namibia: NS1

Rwanda: TBA

8. Registration Number:

Zimbabwe: 2013/24.4.1/4776

Botswana: BOT1602880

Mozambique: 4815

Namibia: 16/24/0126

Rwanda: TBA

9. Prequalification/ Marketing Authorisation Holder and Manufacturer

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